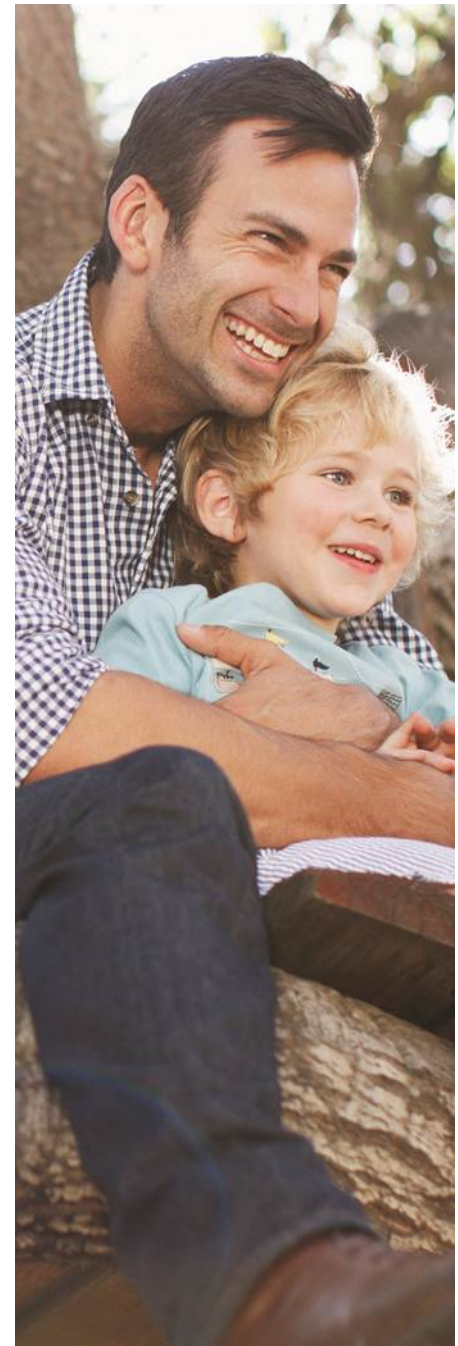


CENTER FOR TOBACCO PRODUCTS STRATEGIC PRIORITIES



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TOBACCO
PRODUCTS

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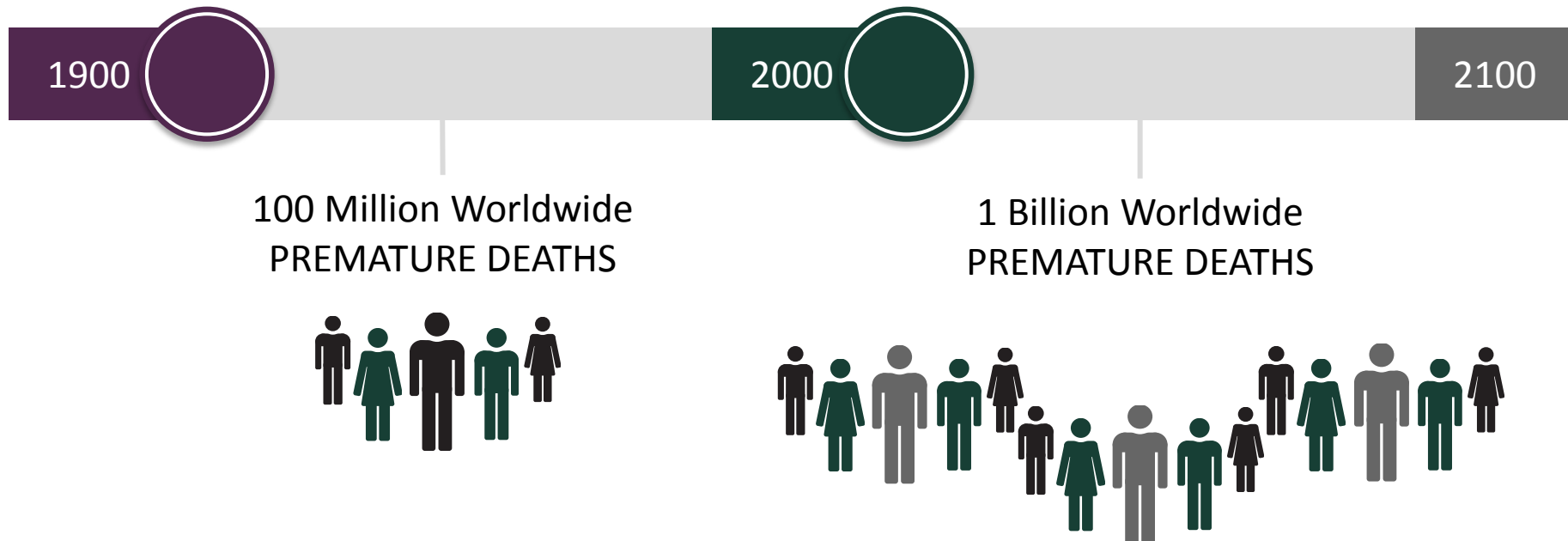
HIGHLIGHTS OF TODAY'S PRESENTATION

- Setting the stage
- Building the foundation
- Pursuing strategic priorities



SETTING THE STAGE

FIGHTING AN UPHILL BATTLE AGAINST DISEASE AND DEATH



PREVENTING THE PREVENTABLE IN THE U.S.

- Despite huge strides, 42 million adults still smoke
- Nearly 500,000 Americans die each year and 16 million more live with disease
- Every day over 3,200 teens smoke their first cigarette
- More than 700 youth become daily smokers



CREATING CHANGE FOR A HEALTHIER FUTURE



BUILDING THE FOUNDATION

CREATING THE BUILDING BLOCKS

Building CTP to achieve programmatic goals

- Human resources, IT, acquisitions, logistics, budget
- Policy analysis
- External communications

Developing foundational rules and guidance

- “Deeming” proposed rule
- User fees proposed rule
- Investigational products
- Testing/reporting/disclosure

Setting and funding a research agenda



PURSuing STRATEGIC PRIORITIES

- Product Standards
- Comprehensive FDA Nicotine Regulatory Policy
- Pre & Post-Market Controls: Regulations & Product Reviews
- Compliance and Enforcement
- Public Education



PRODUCT STANDARDS

IMPLEMENTING ONE OF THE LAW'S MOST POWERFUL TOOLS

- Advancing a product standard strategy that yields strong standards to improve public health and that can withstand legal challenge
- Exploring potential standards for:
 - Addictiveness
 - Toxicity
 - Appeal



COMPREHENSIVE FDA NICOTINE REGULATORY POLICY

LOOKING AT NICOTINE DIFFERENTLY

- Establish an integrated, FDA-wide policy on nicotine-containing products that is public-health based
- Recognize that there is a continuum of nicotine-containing products...and the reality that people smoke for the nicotine but die from the tar
- Implications for tobacco, drug, and device regulatory policy



LOOKING AT NICOTINE DIFFERENTLY

- Related actions include:
 - Finalizing Deeming regulation
 - Developing jurisdiction policy on nicotine-containing products across FDA
 - Working with CDER and CDRH to determine how regulation of therapeutic nicotine products (Rx, OTC, drugs, devices) could evolve
 - Exploring options at CTP for an expedited premarket review policy based on principle of relative toxicity and risk
- Also has implications for HHS policies (e.g. reimbursement)

PRE & POST MARKET CONTROLS: REGULATIONS AND PRODUCT REVIEWS

PROTECTING CONSUMERS



As the regulatory gatekeeper, CTP now stands between tobacco products and consumers

SETTING PRE & POST MARKET POLICY

- Explore developing rules and guidances for:
 - Product review pathways (SE, PMTA, MRTP)
 - Tobacco Product Manufacturing Practices (TPMP)
 - Analytic test method validation
- Continue to establish and then meet performance standards for product reviews

COMPLIANCE AND ENFORCEMENT

ENFORCING THE LAW

- Inspection, investigation, monitoring and review activities
- Initiate appropriate enforcement actions that are supported by evidence
 - Develop and document sufficient evidence to support enforcement actions for violations of the law
 - Expand state inspection program to remaining states and territories
 - Plan for implementation of compliance activities for newly deemed products
 - Implement compliance inspection, education, and enforcement activities on tribal lands

PUBLIC EDUCATION

EDUCATING AT RISK AUDIENCES ON THE DANGERS



10
Million



General “At Risk” Market
Multicultural
Rural
**American Indian/
Alaska Native**
LGBT

Prevention



**Investing in
our Future**



MAXIMIZING USE OF OUR AUTHORITY FOR A HEALTHIER TOMORROW

- Utilize the tools given to us by Congress to maximize their potential and positively impact public health



THANK YOU



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